

AD_____

AWARD NUMBER:
W81XWH-12-2-0117

TITLE:
Project VALOR: Trajectories of Change in PTSD in Combat-Exposed Veterans

PRINCIPAL INVESTIGATOR:
Terence M. Keane, PhD

RECIPIENT:
VA Boston Healthcare System
Research Service (151B)
150 South Huntington Ave.
Boston, MA 02130

REPORT DATE:
October 2013

TYPE OF REPORT:
Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

Approved for public release; distribution is unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

| REPORT DOCUMENTATION PAGE | | | Form Approved OMB No. 0704-0188 | |
|---|------------------|--|------------------------------------|---|
| Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS. | | | | |
| 1. REPORT DATE (DD-MM-YYYY) Š\~âãã2013 | | 2. REPORT TYPE Annual | | 3. DATES COVERED (From - To) 1Š\~âããG012-30Uæ*\æ†âããG€13 |
| 4. TITLE AND SUBTITLE Šã~↓æ'\ÄÜNQŠİÄÜää↓æ'\~ã↔æbÄ~àÄOää^&æÄ↔^ÄŞÜUEÄ↔^ÄO~†âä\ËÓ[*~bæää Üæ\æää^bÄ | | 5a. CONTRACT NUMBER W81XWH-12-2-0117 | | |
| | | 5b. GRANT NUMBER ÛİFVÛÖËFGËGË€FFİ | | |
| | | 5c. PROGRAM ELEMENT NUMBER | | |
| 6. AUTHOR(S) Vgtgpeg'O OMgcpG.'Rj F | | 5d. PROJECT NUMBER | | |
| | | 5e. TASK NUMBER | | |
| | | 5f. WORK UNIT NUMBER | | |
| 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Boston VA Research Institute Inc. 150 South Huntington Ave Research 151B | | 8. PERFORMING ORGANIZATION REPORT NUMBER USAMRMC | | |
| 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Material Command Fort Detrick, Maryland 21702-5012 | | 10. SPONSOR/MONITOR'S ACRONYM(S) | | |
| | | 11. SPONSOR/MONITOR'S REPORT NUMBER(S) | | |
| 12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited. | | | | |
| 13. SUPPLEMENTARY NOTES | | | | |
| 14. ABSTRACT This goal of this project is to develop a large-scale, longitudinal registry of PTSD in combat-exposed OIF/OEF/OND male and female veterans. The objective of the current study is to systematically expand the longitudinal assessment by collecting follow-up data at additional time points for multiple domains of interest. Patterns of longitudinal change in the VALOR cohort will be empirically classified into trajectory subtypes by means of latent growth mixture modeling. The availability of comprehensive data on PTSD symptoms and related exposures and outcomes at multiple time points in a cohort of VA users with and without PTSD provide a unique opportunity to examine a number of hypotheses regarding longitudinal trajectories in combat-exposed veterans. In addition, the large proportion of women in our sample will allow us to examine variation in the associations by gender. | | | | |
| 15. SUBJECT TERMS Risk factors for PTSD. PTSD symptom development and VA healthcare utilization. | | | | |
| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT U | 18. NUMBER OF PAGES 7 |
| a. REPORT U | b. ABSTRACT U | c. THIS PAGE U | | |
| | | | | 19b. TELEPHONE NUMBER (include area code) |

Table of Contents

| | <u>Page</u> |
|---|-------------|
| 1. Introduction | 5 |
| 2. Keywords | 5 |
| 3. Overall Project Summary | 5 |
| 4. Key Research Accomplishments | 5-6 |
| 5. Conclusion | 6 |
| 6. Publications, Abstracts, and Presentations | 6-8 |
| 7. Inventions, Patents and Licenses | 8 |
| 8. Reportable Outcomes | 8 |
| 9. Other Achievements | 8 |
| 10. Quad Report | 9 |

1. INTRODUCTION:

Project VALOR is a large-scale, longitudinal registry of PTSD in combat-exposed OIF/OEF/OND male and female veterans. The objective of the current study is to systematically expand the longitudinal assessment by collecting follow-up data at additional time points for multiple domains of interest. Patterns of longitudinal change in the VALOR cohort will be empirically classified into trajectory subtypes by means of latent growth mixture modeling. The availability of comprehensive data on PTSD symptoms and related exposures and outcomes at multiple time points in a cohort of VA users with and without PTSD provide a unique opportunity to examine a number of hypotheses regarding longitudinal trajectories in combat-exposed veterans. In addition, the large proportion of women in our sample will allow us to examine variation in the associations by gender.

Using baseline and follow-up data from participants in Project VALOR, we will evaluate the following specific aims:

1. Examine trajectories of PTSD symptomatology and diagnosis by chart and diagnostic interview assessments in combat-exposed men and women.
2. Examine the nature and extent of military sexual trauma (MST) in combat-exposed men and women who have utilized the VA Healthcare System, including the contribution of MST to PTSD symptoms and diagnosis.
3. Examine associations of PTSD, mTBI, major depressive disorder (MDD), and treatment utilization in relation to changes in suicidal ideation.

2. KEYWORDS:

Post-traumatic stress disorder (PTSD), military sexual trauma (MST), suicide, combat-exposed veterans, PTSD trajectory, longitudinal, VA utilization

3. OVERALL PROJECT SUMMARY:

In quarter one of this year the protocol and the manual of operations were finalized in accordance with the recommendations of our Scientific Advisory Board in preparation for submission to the local IRBs. In addition, candidates were identified to fill vacant positions. In quarter two, our protocol and manual of operation were submitted to the IRB and vacant positions were filled. In addition, training of personnel in anticipation of recruitment in the fourth quarter began. Final approval from the VA Boston Healthcare System IRB was received in the first month of quarter three and our application for initial review was submitted to HRPO in the third month of the quarter. Additional vacant positions were filled and training of personnel in anticipation of recruitment in the fourth quarter continued. In the first month of the fourth quarter final approval was received from HRPO. In addition, subject recruitment and data collection began in the fourth quarter. At this point, 72 participants have completed the study and 156 participants have been consented. Throughout the year, we have continued to analyze data from Phase I of the project for multiple manuscripts and presentations in preparation

4. KEY RESEARCH ACCOMPLISHMENTS:

- Study measures and procedures were finalized and approved.
- Recruitment, consenting participants, and data collection are under way.

5. CONCLUSION:

The PTSD registry will provide information to assist researchers, military leaders, and treatment providers to better understand PTSD and related problems, with specific focus on the course of the disease, suicidal ideation, and military sexual trauma. This knowledge will be of benefit to health care providers, policy makers and current service members as well as victims of trauma in the broader community. It will include:

- Evaluation of long-term outcomes of PTSD;
- A more accurate assessment of current theoretical models of symptom development, and;
- Documentation of health resource utilization and development of a database that would serve as a resource for health services planning and policy.

Furthermore, this study will contribute:

- The formation of a potential cohort of subjects for ancillary studies, ranging from genomic influences to quality of life and psychosocial outcomes, as well as future clinical trials;
- The creation of a representative sample of PTSD OEF/OIF Veterans who use the VA medical system, available for use in epidemiologic studies, particularly for comparisons with active duty and other Veteran or civilian populations;
- Utility to clinicians, patient advocacy groups, and health policy planners;
- Publications and dissemination of the registry results to provide a representative perspective of what is achieved in actual current care settings, thereby augmenting outcomes data from clinical trials.

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

PUBLICATIONS

1. Rosen, R.C., Marx, B.P., Maserejian, N.N., Holowka, D.W., Gates, M.A., Sleeper, L.A., Vasterling, J.J., Kang, H.K. & Keane, T.M.. (2012). Project VALOR: Design and Methods of a Longitudinal Registry of Posttraumatic Stress Disorder (PTSD) in Combat-Exposed Veterans in the Afghanistan and Iraqi Military Theaters of Operations. *International Journal of Methods in Psychiatric Research*, 21(1): 5–16.
2. Gates, M.A., Holowka, D.W., Vasterling, J.J., Keane, T.M., Marx, B.P. & Rosen, R.C. (2012). Posttraumatic Stress Disorder in Veterans and Military Personnel: Epidemiology, Screening, and Case Recognition. *Psychological Services*, 9(4):361-382.

3. Miller, M. W., Wolf, E. J., Kilpatrick, D., Resnick, H., Marx, B. P., Holowka, D. W., Keane, T. M., Rosen, R. C., & Friedman, M. J. (2012, September 3). The Prevalence and Latent Structure of Proposed DSM-5 Posttraumatic Stress Disorder Symptoms in U.S. National and Veteran Samples. *Psychological Trauma: Theory, Research, Practice, and Policy*. Advance online publication.
4. Wisco, B.E., Marx, B.P., Holowka, D.W., Vasterling, J.J., Han, S.C., Chen, M.S., Gradus, J.L., Nock, M.K., Rosen, R.C., Keane, T.M. (2013) Traumatic brain injury, PTSD, and current suicidal ideation among Iraq and Afghanistan Veterans. Submitted.
5. Holowka, D.W., Marx, B.P., Margaret A. Gates, M.A., Rosen, R.C., Keane, T.M. (2013). Medical Chart PTSD Diagnostic Concordance among Iraq and Afghanistan Veterans. Submitted.

PRESENTATIONS

1. Chen, M.S., Han, S.C., Holowka, D.W., Marx, B.P., Gates, M.A., Rosen, R.C. & Keane, T.M. (2012, November). Problem Drinking Moderates the Effect of Social Support on PTSD and Suicide Risk. Poster session to be presented at the annual meeting of the International Society for Traumatic Stress Studies, Los Angeles, CA.
2. Chen, M.S., Holowka, D.W., Marx, B.P., Gates, M.A., Rosen, R.C. & Keane, T.M. (2012, November). Anger Mediates the Relationship between Combat Exposure and Functioning. Poster session presented at the annual meeting of the International Society for Traumatic Stress Studies, Los Angeles, CA.
3. Han, S.C., Chen, M.S., Fink, H.L., Holowka, D.W., Marx, B.P., Gates, M.A., Rosen, R.C. & Keane, T.M. (2012, November). PTSD Symptoms and Parental Functioning among Male and Female OEF/OIF Veterans. Poster session presented at the annual meeting of the International Society for Traumatic Stress Studies, Los Angeles, CA.
4. Lachowicz, M.J., Franz, M.R., Gorman, K.R., Holowka, D.W., Marx, B.P., Gates, M.A., Rosen, R.C., Keane, T.M. (2012, November). Deployment and post-deployment experiences in Iraq-deployed soldiers: comparison of soldiers deployed during the Iraq invasion, insurgency, and surge. Poster presented at the 46th annual convention of the Association for Behavioral and Cognitive Therapies, National Harbor, MD.
5. Holowka, D.W. (2013, April). Concordance between PTSD diagnoses in electronic medical records and standardized diagnostic interviews among veterans deployed to Iraq and Afghanistan. Presented at the Anxiety Disorders and Depression Conference.

6. Keane, T.M. and Rosen, R.C. Symposium Chairs. (2013, April). The impact and outcomes of PTSD on combat exposed veterans: Project VALOR. Presented at the Anxiety Disorders and Depression Conference.
7. Keane T.M. (2013, April). Prevalence and latent structure of proposed DSM-5 Posttraumatic Stress Disorder symptoms among veteran enrolled in Project VALOR. Presented at the Anxiety Disorders and Depression Conference.
8. Marx, B.P. (2013, April). Posttraumatic Stress Disorder, mild traumatic brain injury and psychosocial functioning among Iraq and Afghanistan veterans. Presented at the Anxiety Disorders and Depression Conference.
9. Rosen, R.C. (2013, April). Gender effects in PTSD presentation and outcomes: findings from a large cohort of male and female OEF/OIF veterans in Project VALOR. Presented at the Anxiety Disorders and Depression Conference.
10. Fang, S, Rosen, R, Holowka, D.W., Marx, B., Vasterling, J., Litman, H., Akeroyd, J., Keane, T. (2013, June) Psychosocial Outcomes in OEF/OIF Veterans with PTSD: Initial Findings from the VALOR Registry. Presented at the Society for Epidemiologic Research.

7. INVENTIONS, PATENTS AND LICENSES:

Nothing to report

8. REPORTABLE OUTCOMES:

Nothing to report

9. OTHER ACHIEVEMENTS:

Nothing to report

Project VALOR: Trajectories of Change in PTSD in Combat-Exposed Veterans

Annual Report

W81XWH-12-2-0117



PI: Terence M. Keane, PhD

Org: VA Boston Healthcare System

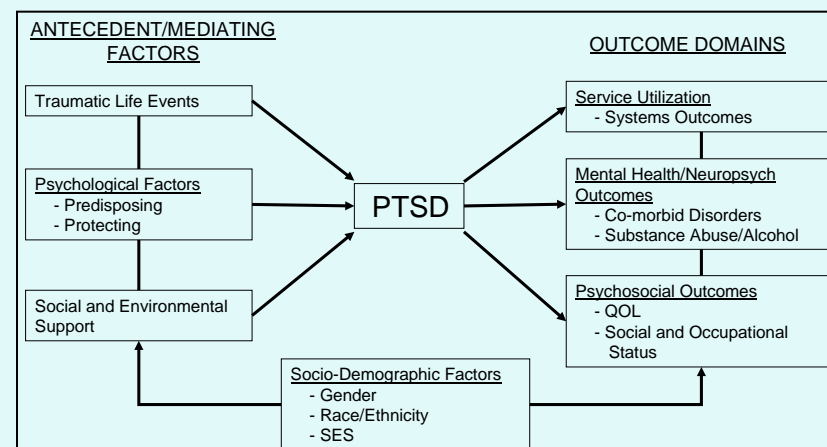
Award Amount: \$3,295,994

Study/Product Aim(s)

- Examine trajectories of PTSD symptomatology and diagnosis by medical chart abstractions and diagnostic interview assessments in combat-exposed men and women.
- Examine the nature and extent of military sexual trauma (MST) in combat-exposed men and women who have utilized the VA Healthcare System, including the contribution of MST to PTSD symptoms and diagnosis.
- Examine associations of PTSD, mTBI, major depressive disorder (MDD), and treatment utilization in relation to changes in suicidal ideation.

Approach

To develop the first longitudinal registry of combat-exposed men and women with post-traumatic stress disorder (PTSD), 1649 participants from across the country will complete a second follow-up round of online questionnaires, and telephone interviews. We will also have access to our participants' electronic VA medical charts.



Data collection began in 09/2013 and we are currently meeting our recruitment goals. Analysis of Phase 1 data is ongoing.

Timeline and Cost

| Activities | CY | 12 | 13 | 14 | 15 |
|---------------------------------------|----|---|---|----------------|---|
| IRB and HRPO Approval | | <div style="width: 100%; height: 10px; background-color: #90EE90;"></div> | | | |
| Data Collection (Rounds 1-3) | | | <div style="width: 100%; height: 10px; background-color: #90EE90;"></div> | | |
| Analysis of Data (Phases 1 and 2) | | <div style="width: 100%; height: 10px; background-color: #90EE90;"></div> | | | |
| Preparation of Dataset for Future Use | | | | | <div style="width: 100%; height: 10px; background-color: #90EE90;"></div> |
| Estimated Budget (\$K) | | \$759.8 | \$852.5 | \$875.5 | \$808.2 |

Goals/Milestones

CY12 Goal – Start Data Collection

- ☒ Training of study staff
- ☒ Continue analysis of data from Valor 1

CY13 Goals – Continue Data Collection

- ☐ Collection of Round 1 data
- ☐ Continue analysis of data from Valor 1 and 2

CY14 Goal – Continue Data Collection

- ☐ Finish collection of Round 2 data
- ☐ Start Round 3 data collection

CY15 Goal – Complete Data Collection and Analyze Data

- ☐ Finish collection of Round 3 data
- ☐ Continue data analysis and prepare database for future use

Budget Expenditure to Date

Projected Expenditure: \$759,832.00

Actual Expenditure: \$423,563.00

Updated: 10/15/13